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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/014,291	10/26/2001	Stephan von Horsten	20488/12 U.S.	9996
7590		03/03/2004	EXAMINER	
Mark A. Hofer, Esq.		CHERNYSHEV, OLGA N		
Brown, Rudnick, Freed & Gesmer		ART UNIT		
One Financial Center		PAPER NUMBER		
Boston, MA 02111		1646		

DATE MAILED: 03/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/014,291

**Applicant(s)**

HORSTEN ET AL.

**Examiner**

Olga N. Chernyshev

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                         |                                                                             |
|-----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                                |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____                                                             | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Response to Amendment***

1. Claims 1-13 have been amended as requested in the amendment of Paper filed on September 22, 2003. Claims 1-13 are pending in the instant application.

Claims 1-13 are under examination in the instant office action.

2. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

4. Applicant's arguments filed on September 22, 2003 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

### ***Claim Rejections - 35 USC § 112***

5. Claims 1, 3-6, 9 and 11-12, as amended, stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for reasons of record in section 6 of Paper No. 7. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant traverses the rejection on the premises that the instant specification provides "numerous examples that contain dosing and criteria of evaluation of such dosing within various animal studies" (second paragraph at page 8 of the Response) and, further, that information within Examples 1-4 fully satisfies the requirements of 35 USC 112, first paragraph. These

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arguments have been fully considered but are not deemed to be persuasive for the following reasons.

Claims 1, 3-6, 9 and 11-12, as amended, are drawn to a method for treating the psychophysiological effects of stress including anxiety by applying to the central nervous system a therapeutically effective amount of an inhibitor of the DP IV enzyme. The instant specification fails to define any specific criteria, which clearly identify “psychophysiological effects of stress” one would wish to modulate. For example, Examples 1-4 of the instant specification describe the results of administration of DPIV inhibitor using specific substrains of rats as an animal model for anxiety and stress. Different behavioral parameters related to stress are evaluated. However, claims 1, 3-6, 9 and 11-12 employ the recitation “psychophysiological effects of stress including anxiety” as a limitation. It is obvious that without defining criteria, which constitute “psychophysiological effects of stress”, one skilled in the art would have to engage in undue experimentation with no assurance of success to discover how to evaluate which parameters of “psychophysiological effects of stress” are treated by application of an inhibitor of DP IV enzyme.

Applicant is advised that the instant claims are rejected under 35 U.S.C. 112, first paragraph, for failing to provide enablement for the claimed invention, which is fundamentally different from utility requirement. Therefore, Applicant’s quotation of case law pertained to the utility rejection under 35 U.S.C. 101 appears to be misplaced (page 8 of the Response). Also, Applicant’s request for the Examiner “to provide an affidavit under 37 C.F.R. § 107 (b)” (page 9 of the Response) is moot in view of the absence of § 107 (b) in Title 37 of Code of Federal Regulations.

6. Claims 1 and 2 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for reasons of record in section 11 of Paper No. 7. Briefly, the claims use the term “DP IV – like enzyme”, which renders claims indefinite because it is not obvious, which enzymes are to be included or excluded by the limitation “like”. Applicant argues that the term “like” is clearly defined in the instant specification and also in the plain dictionary (section D, page 10 going to page 11 of the Response). These arguments have been fully considered but are not deemed persuasive because the instant specification fails to provide a clear definition of which enzymes are included or excluded in the recited genus of “DP IV – like enzyme(s)” thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d). For example, it appears that any peptidase could be defined as a “DP IV – like enzyme” because inhibition of its activity “will result in a reduction or delay in the decrease of the concentration of functionally active NPY” (bottom at page 10 of the Response).

7. Claim 2, as amended, is vague and indefinite for reasons of record in section 13 of Paper No. 7. Briefly, the metes and bounds of the recitation “other substrates sharing similar properties as neuropeptide Y” cannot be determined from the claim. It is not clear and not defined in the instant specification what “other substrates” or what “similar properties of neuropeptide Y” are intended by the claim.

8. Claim 6 recites the limitation "DP IV inhibitors" in claim 1. There is insufficient antecedent basis for this limitation in the claims, see reasons of record in section 16 of Paper No. 7.

9. Claims 3-5, 7-13 are indefinite for being dependent from indefinite claims.

***Claim Rejections - 35 USC § 102***

10. Claims 2, 7-8, 10 and 13 stand rejected under 35 U.S.C. 102(b) as being anticipated by Powers et al. (WO 95/2961, 1995, Document BL, IDS of Paper No.2) for reasons of record in section 18 of Paper No. 7.

Applicant traverses the rejection on the premises that “[u]nlike Applicant’s claimed invention, Powers is completely devoid of any disclosure teaching or making obvious the use of DP IV inhibitors for the treatment of central nervous system” (section D on page 12 of the Response). This argument has been fully considered but is not persuasive because, as fully explained in the previous office action, Powers discloses administration of inhibitors of dipeptidyl peptidase IV, such administration leads to the decrease of enzymatic activity of DPIV and, consequently, to the reduction of degradation of its natural endogenous substrate. Applicant is reminded that claim 2 is an independent claim and that claims 2, 7-8, 10 and 13 are directed to a method for reducing degradation of NPY and not “to the “treatment of psychophysiological effects of stress”, as stated in section B on page 10 of the Response.

11. Claims 1, 3-6, 9 and 11-12 stand rejected under 35 U.S.C. 102(b) as being anticipated by Powers et al. (WO 95/2961, 1995, Document BL, IDS of Paper No.2) for reasons of record in section 19 of Paper No. 7.

Applicant argues that because three references were used for the instant rejection, such “combination of references makes this rejection under 35 USC 102 (b) improper” (beginning at page 13 of the Response). Applicant is advised that the instant claims stand rejected under 35 U.S.C. 102(b) as being anticipated by Powers et al. alone and that the references of Demuth and

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Lader are provided only to characterize scientific knowledge in the art and not for motivation to combine the references. See MPEP 2131.01.

Applicant further argues that “none of the cited references, either alone or in combination disclose or suggest the “treatment of psychophysiological effects of stress” resulting from central nervous system disorders such as anxiety using an inhibitor of DP IV” (section F at page 14 of the Response). Applicant’s arguments have been fully considered but are not deemed to be persuasive because administration of a therapeutically effective amount of an inhibitor of the DPIV enzyme is known and fully disclosed in prior art by publication of Powers. Therefore, because the document of Powers fully discloses the step of administration of DPIV inhibitors, the results of the same procedure are reasonably expected to be the same, and, consequently, such administration of DPIV inhibitors would lead to treatment of “psychophysiological effects of stress”. In the decision *Ex parte Novitski*, 26 USPQ2d 1389 (Bd. Pat. App. & Inter. 1993) the court held that the discovery of an inherent property of a prior art process cannot serve as a basis for patenting that process. Therefore, Powers et al. anticipate claims 1, 3-6 and 11-12 of the instant invention.

12. Claims 1-13 stand rejected under 35 U.S.C. 102(e) as being anticipated by Demuth et al., US Patent 6,319,893, 11/20/2001, filed 08/02/1999 for those reasons of record in section 20 of Paper No. 7.

Applicant submits that “Demuth ‘893 is completely devoid of any disclosure suggesting the use of DP-IV inhibitors for the treatment of central nervous system disorders”. This arguments is not considered to be persuasive for reasons fully explained in previous office action of Paper No. 7 and reasons of record in sections 10-11 of the instant office action. Demuth et al.

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describe administration to the mammal a therapeutically effective amount of an inhibitor of DPIV. The instant claims encompass the same procedure, such as administration of an inhibitor of DPIV. One would reasonably conclude that the results of the same procedure are expected to be the same, regardless of the disclosure of every effect of such procedure. Therefore, the discovery of the inherent property of inhibitors of DPIV enzymes as modulators of “psychophysiological effects” of stress cannot serve as a patentably distinguishing feature of the instant invention. (See *Ex parte Novitski*, 26 USPQ2d 1389 (Bd. Pat. App. & Inter. 1993))

### ***Double Patenting***

13. Claims 1-13 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6,319,893 for reasons of record in section 22 of Paper No. 7. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

Applicant argues that “the claimed subject matter of the rejected claims differ from that of the claims of Demuth ‘893, [because] claims 1-13 are directed to methods of treatment of central nervous system disorders, while Demuth ‘893 discloses a “method of raising the blood sugar level in a mammal having hypoglycemia by reducing degradation of glucagons” (last paragraph at page 16). These arguments have been fully considered but are not deemed to be persuasive for reasons of record in sections 18-22 of Paper No. 7 and reasons of record in sections 10-12 of the instant office action. Briefly, because ‘893 patent fully discloses the step of administration of DPIV inhibitors for alteration of blood sugar levels due to reduction of degradation of DPIV substrate and in view of *Ex parte Novitski*, the claims of ‘893 patent



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directed to administration of DPIV inhibitors to alter blood sugar levels inherently encompass therapy of anxiety disorders.

### ***Conclusion***

14. No claim is allowed.

15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (571) 272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)0. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 872-9306. If this number is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (571) 273-0870. Official papers should NOT be faxed to (571) 273-0870.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Olga N. Chernyshev, Ph.D.



JOHN ULM  
PRIMARY EXAMINER  
GROUP 1600